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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,879	11/20/2000	Tatsuya Tamura	TAMURA-5	4195
1444	7590	01/15/2004	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			MAIER, LEIGH C	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/700,879	<b>Applicant(s)</b> TAMURA ET AL.	
	<b>Examiner</b> Leigh C. Maier	<b>Art Unit</b> 1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 31 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1,3,5-12 and 17-25 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1,3,5-12 and 17-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☒ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
     a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Status of the Claims***

Claim 9 has been amended. Claim 25 is newly presented. Claims 1, 3, 5-12, and 17-25 are pending. Any objection or rejection not specifically repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new grounds of rejection.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites the bond between the therapeutic agent and HA is selected from a group consisting of an amide bond, an ether bond and a sulfide bond. However, this claim depends from claim which requires a spacer between the therapeutic agent and HA. Therefore, there is no direct bond between the therapeutic agent and the HA, thus rendering the claim vague and indefinite.

***Claim Rejections - 35 USC § 102***

Claims 1, 5, 8, 11, 19, 23, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by DICKERSON et al (US 5,677,276).

The reference teaches a conjugate comprising HA linked to an RGD peptide via a spacer. See Figure 2 and col 11, lines 1-35. The compounds are disclosed as having utility in promoting wound healing and tissue degeneration in bone and cartilage. See abstract and col 10, lines 12-21. The reference suggests application of the agents at the site of matrix destruction. See col 9, lines 28-41.

***Claim Rejections - 35 USC § 103***

Claims 1, 3, 5-12, and 17-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over DICKERSON et al (US 5,677,276) and GALLARDY et al (WO 92/09556).

The invention is as set forth in the previous Office action.

DICKERSON teaches as set forth above. The reference does not specifically exemplify the administration of the disclosed compounds for the treatment of joint diseases.

GALLARDY teaches as set forth in the previous Office action. The compounds also have utility in the promotion of wound healing. See paragraph bridging pages 12 and 13.

As set forth above, DICKERSON does not specifically exemplify the treatment of joint disorders. However, one of ordinary skill that a therapeutic agent capable of promoting regeneration of cartilage would be reasonably be expected to have utility in the treatment of joint disorders. Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the DICKERSON compounds by substituting hydroxamic

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acid derivative, including those discussed in the previous Office action, for the treatment of joint disorders or the promotion of wound healing. One of ordinary skill would reasonably expect success in making such a modification and administration to a patient in need thereof for said disorders.

With regard to claims 20 and 21, these are product by process claims. The claim is a product-by-process claim. However, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In using the process taught by DICKERSON, the product derived would be the same although the process differs in the sequence of the reaction steps.

Claims 1, 3, 5-12, and 17-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over DICKERSON et al (US 5,677,276) and GALLARDY et al (WO 92/09556) in further view of (1) BEMIS et al (US 6,147,080) or (2) WUNDERLICH et al (US 6,066,332).

The invention is as set forth in the previous Office action. Claim 18 recites the use of a COX-2 inhibitor, MMP inhibitor, or an antirheumatic agent.

DICKERSON and GALLARDY teach as set forth above. The references do not teach the full scope of the therapeutic agents recited in claim 18.

BEMIS and WUNDERLICH teach as set forth in the previous Office action.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to add another agent having utility in the treatment of arthritis, such as the

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anti-inflammatories taught by BEMIS and/or WUNDERLICH for the combined effects. One of ordinary skill would reasonably expect success in making such a modification.

***Examiner's hours, phone & fax numbers***

*Please note that the examiner for this application has changed.* Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (703) 308-4525. The examiner can normally be reached on Tuesday, Wednesday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (703) 308-4624, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.



Leigh C. Maier  
Patent Examiner  
January 12, 2004